



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,435	12/12/2006	Daisuke Shoji	P30635	8794
7055 7590 11/23/2010 GREENBLUM & BERNSTEIN, P.L.C. 1950 ROLAND CLARKE PLACE RESTON, VA 20191				
EXAMINER				
WANG, CHUN CHENG				
ART UNIT		PAPER NUMBER		
1763				
NOTIFICATION DATE		DELIVERY MODE		
11/23/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com

pto@gbpatent.com

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/599,435

Applicant(s)

SHOJI ET AL.

Examiner

Chun-Cheng Wang

Art Unit

1763

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 10 November 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 1 and 3.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☒ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____.
13. ☒ Other: See Continuation Sheet.

/Chun-Cheng Wang/
Examiner, Art Unit 1763

/Ling-Siu Choi/
Primary Examiner, Art Unit 1762

Continuation of 11. does NOT place the application in condition for allowance because:

Claims 1 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kikuchi et al. ("Porous Body Preparation of Hydroxyapatite/Collagen Nanocomposites for Bone Tissue Regeneration, Key Engineering Materials, Vols 254-256 (2004), pp 561-564).

Kikuchi disclose elastic porous bodies were fabricated from hydroxyapatite/collagen nanocomposite fibers by lyophilization with the use of collagen as a binder (Abstract). The composite fibers, collagen solution and water are mixed and gelled. The gelled mixtures are frozen at -10, -20, -30, -40 and -80°C respectively and lyophilized followed by cross-linkage (Materials and Method, lines 6-8, pp562). The mean pore size increases with increasing freezing temperature. The pore in the porous body prepared by lyophilization is formed by removal of ice crystals between the Hap/Col fibers, i.e., the pore size depends on growth behavior of the ice crystals. The rapid decreasing of temperature (e.g. shorter solidification time) of the gelled mixture resulted in a large amount of ice crystals and ice crystals between the fibers became smaller (read on solidification time vs. pore size relation) (Results and Discussion, lines 1-4, pp 562). Kikuchi clearly disclose using freezing temperature to control the pore size of the fibrous apatite/collagen composite, which is the same conclusion from Fig. 3 of instant application.

Kikuchi is silent on charting solidification time, Sb, vs. average pore diameter, Dav and freezing-environment temperature, T0, vs. solidification time.

Since Kikuchi clearly disclose using freezing temperature to control the pore size of the fibrous apatite/collagen composite and the relationship between solidification time vs. pore size, the solidification time Sb can also be measured and use it to plot the charts of Sb vs. Dav and T0 vs. Sb. For a system that the complete solidified state can not be easily monitored, the Sb is a convenient indicator for the completion of solidifying treatment.

In light of such benefit, it would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains to utilize the solidification time and freezing-environment temperature chart to control the pore size..

Continuation of 13. Other:

The Declaration under 37 C.F.R. 1.132 of Daisuke Shoji and the argument filed on 11/10/2010 are not convincing.

Applicant argued: The Declaration further demonstrates that by first determining a specific solidification time based on a specific freezing-environment temperature (Figure 6A), and then using said determined solidification time to determine a corresponding average pore diameter (206 µm) (Figure 8A), that the actually measured average pore diameter (experimental pore diameter) is very close to said calculated pore diameter (205.3 µm). In comparison, it is shown in the Declaration that the method according to Kikuchi (see Declaration, Figure 9A) leads to not such a close match between calculated pore diameter (216 µm) and experimental pore diameter (205.3 µm). Response: The difference between the calculated pore diameter and measured pore diameter is 0.7 µm for the instant application and is 10.7 µm for the Kikuchi method. Applicant also indicated the pore diameter standard deviations (STD) for different average pore diameter (Avg) as 97±71 µm, 330±150 µm and 619±411 µm (Avg±STD; See TABLE 3 of the instant Specification). The difference between the calculated pore diameter according to instant method and the Kikuchi method is 10 µm which is not significant or more accurate when compared with measurement of the pore diameter standard deviations that are greater than 71 µm.